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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRAINTREE LABORATORIES, INC., Plaintiff, v. NOVEL LABORATORIES, INC., Defendant/Counterclaim Plaintiff.	Civil Action No. 3:11-cv-01341-PGS-LHG **ANSWER AND AMENDED COUNTERCLAIMS**

Defendant Novel Laboratories, Inc. ("Novel") answers Plaintiff Braintree Laboratories, Inc.'s ("Braintree") Complaint for Patent Infringement ("Complaint") as follows:

NATURE OF THE ACTION

Novel admits that the Complaint purports to set forth a claim for patent infringement and that this action concerns Novel's ANDA No. 202511, but otherwise denies the allegations in this paragraph.

PARTIES

1. Novel lacks sufficient information to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

2. Admitted.

3. Novel admits that upon final FDA approval of ANDA No. 202511, Novel may make, offer to sell and/or sell the generic product that is the subject of ANDA No. 202511 throughout the United States, but otherwise denies the allegations in this paragraph.

JURISDICTION AND VENUE

4. Admitted.

5. Admitted.

6. Admitted.

7. Novel admits that it regularly does business in New Jersey and with its sister company GAVIS places goods into the stream of commerce in the United States and in New Jersey, and sells, markets and distributes medicine to all major customers in the United States, but otherwise denies the allegations in this paragraph.

8. Admitted.

BACKGROUND

9. Admitted.

10. Novel admits that the '149 patent is listed in the Orange Book, but otherwise denies the allegations in this paragraph.

THE '149 PATENT

11. Novel admits that Braintree purports to be the lawful owner of the '149 patent, that the '149 patent was the subject of an *ex parte* reexamination, that a reexamination certificate was issued, and that certain claims were cancelled and amended, but defendant otherwise denies the allegations of this paragraph.

12. The allegations in this paragraph constitute legal conclusions to which no response is required and defendant denies them.

13. Novel lacks sufficient information to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

14. Novel lacks sufficient information to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

INFRINGEMENT BY NOVEL

15. Admitted.

16. Admitted.

17. The allegations in this paragraph constitute legal conclusions to which no response is required and defendant denies them.

18. The allegations in this paragraph constitute legal conclusions to which no response is required and defendant denies them.

19. Novel lacks sufficient information to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

COUNT I (INFRINGEMENT OF THE '149 PATENT BY NOVEL)

20. Novel restates and incorporates by reference each of its responses to the paragraphs above as if set forth here.

21. Denied.

22. Denied.

23. Denied.

24. Denied.

25. Denied.

26. Denied.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

1. Braintree has failed to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

2. The product set forth in Novel's ANDA No. 202511 has not infringed and does not infringe the claims of the '149 patent.

THIRD AFFIRMATIVE DEFENSE

3. One or more claims of the '149 patent are invalid for failure to satisfy at least one of the conditions for patentability specified in Title 35 of the United States Code, including, among others, §§ 101, 102, 103 and/or 112.

ADDITIONAL AFFIRMATIVE DEFENSES

4. There may be additional defenses to Braintree's claims that are currently unknown to Novel. Accordingly, Novel reserves the right to amend its Answer and Counterclaims to allege additional defenses and/or counterclaims in the event discovery of additional information indicates that such defenses are appropriate.

COUNTERCLAIMS

PARTIES

1. Novel is a Delaware corporation having a principal place of business at 400 Campus Drive, Somerset, New Jersey 08873.

2. Braintree is a Massachusetts corporation having a principal place of business at 60 Columbian Street West, Braintree, Massachusetts 02185-0929.

JURISDICTION AND VENUE

3. There is an actual and justiciable controversy between the parties regarding Braintree's claims against Novel and U.S. Patent No. 6,946,149 (the " '149 patent"), and therefore, this Court has subject matter jurisdiction over Novel's counterclaims under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, 28 U.S.C. §§ 1331 and 1338, and 35 U.S.C. § 292.

4. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c), and because Braintree has subjected itself to the jurisdiction of this Court by filing suit and asserting its claims against Novel.

FIRST COUNTERCLAIM

(Declaratory Judgment for Non-Infringement)

5. Paragraphs 1-4 are hereby incorporated by reference as if fully set forth here.

6. The product set forth in Novel's ANDA No. 202511 does not infringe the claims of the '149 patent.

7. Braintree's filing of the Complaint asserting infringement of the '149 patent has injured and damaged Novel.

8. Novel is entitled to a declaratory judgment in its favor that the product set forth in Novel's ANDA No. 202511 has not infringed and does not infringe the claims of the '149 patent.

SECOND COUNTERCLAIM

(Declaratory Judgment for Invalidity)

9. Paragraphs 1-8 are hereby incorporated by reference as if fully set forth here.

10. The '149 patent is invalid for failing to comply with one or more of the requirements for patentability under 35 U.S.C. §§ 101, *et seq*.

11. Novel is entitled to a declaratory judgment in its favor that the claims of the '149 patent are invalid.

THIRD COUNTERCLAIM

(Counterclaim for False Marking under 35 U.S.C. § 292)

12. Paragraphs 1-11 are hereby incorporated by reference as if fully set forth here.

13. 35 U.S.C. § 292(a) provides for a civil penalty of up to $500 for falsely marking an "unpatented article" with a U.S. Patent with the intent of deceiving the public. An article is an unpatented article when it is not covered by any claim of the patent marking the article.

14. Congress passed the Leahy-Smith America Invents Act (H.R. 1249) (the "AIA") passed on September 8, 2011, which became Public Law No. 122-29 on September 16, 2011. Among several other provisions, AIA § 16(b) amends 35 U.S.C. § 292 effective September 16, 2011, retroactively applying to all currently pending cases.

15. After amendment by the AIA, Section 292(a) provides that only the United States may sue for the false marking civil penalty of up to $500. 35 U.S.C. § 292(b). As to third party claims, however, the AIA provides that "[a] person who has suffered a competitive injury as a result of violation of this section may file a civil action in a district court of the United States for recovery of damages adequate to compensate for the injury."

A. THE CLAIMS OF THE '149 PATENT

16. On April 30, 2002, Braintree filed patent application No. 10/135,857 with the U.S. Patent and Trademark Office ("PTO"). As filed, the application named Mark vB. Cleveland, Ph.D. ("Dr. Cleveland") as the sole inventor. Seven years later, on November 11, 2009, Braintree requested that the PTO correct inventorship of the '149 patent to include John S. Fordtran ("Dr. Fordtran") as an inventor.

17. On September 20, 2005, the '149 patent issued with 23 claims directed to compositions and methods for colon cleansing techniques "to prepare the colon for surgical or diagnostic procedures."

18. Braintree filed a request with the PTO for ex parte reexamination of claims 1 and 6 of the '149 patent on October 15, 2008. In connection with the reexamination request, Braintree amended the claim limitation "a small volume," present in composition claims when issued, to recite "from about 100 ml to about 500 ml." An ex parte reexamination certificate issued under 35 U.S.C. § 307 on June 30, 2009, cancelling claims 1, 6, 8, 9, 13, 14, 17 and 21, and amending claims 2-4, 7, 10, 15 and 18.

19. As amended, independent claim 15 recites:

> A composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution comprising an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.

Independent claim 18 is similar to claim 15 but requires "an aqueous hypertonic solution consisting essentially of" effective amounts of each of Na_2SO_4, $MgSO_4$, and K_2SO_4. Independent claims 2 and 7 cover similar compositions that further include PEG. The patent also includes dependent claims directed to methods of inducing colonic purgation by administering compositions claimed in claims 2, 7, 15, and 18.

20. The Federal Circuit has established clear rules for interpreting the scope of patent claims. Words used in a patent claim carry their ordinary and customary meaning as understood by a person of ordinary skill in the art reading the claim in the context of the entire patent specification, including other claims.

21. But a patentee may indicate a clear intention to impart a special meaning for a word used in a claim term that differs from its ordinary and customary meaning. A statement such as "I define ___ to mean ___" is sufficient, but not necessary, to indicate an

inventor's intent to act as his own lexicographer. In such an instance, when the inventor acts as his own lexicographer, the patentee's definition governs and determines the scope of the claim term, even if it is inconsistent with its ordinary meaning. This is well-established patent law and Braintree is well aware of this law.

22. Each claim of the '149 patent covers compositions "comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution." The ordinary and customary meaning of this claim limitation requires a composition of between about 100 ml and about 500 ml. The metric to English conversion of this volume range corresponds approximately to about 3.4 to about 16.9 fluid ounces.

23. Each claim of the '149 patent requires that "the composition does not produce any clinically significant electrolyte shifts." Column 2 of the '149 patent specification states that

> [t]he terms 'clinically significant' as used herein are meant to convey alterations in blood chemistry that are outside the normal upper or lower limits of their normal range or other untoward effects.

This disclosure is an example of a patentee acting as his own lexicographer to impart a particular meaning to a claim term that defines its scope. The '149 patent inventors acted as their own lexicographer in defining the term "clinically significant."

B. BRAINTREE MARKS SUPREP WITH THE '149 PATENT

24. On or about July 1, 2008, Braintree submitted a new drug application (NDA) to the Food and Drug Administration ("FDA") under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate, magnesium sulfate) Oral Solution ("SUPREP").

25. On August 5, 2010, the FDA approved NDA No. 022372, Braintree's NDA for SUPREP.

26. The FDA Orange Book is a paper and electronic document that the FDA maintains and publishes on behalf of the United States government. The FDA Orange Book contains selected information about all pharmaceutical products that the FDA has approved for marketing in the United States after safety and efficacy review.

27. The patent and exclusivity information section of the Orange Book lists, for each pharmaceutical product published therein, any United States patent(s) asserted by the owner or licensee of an FDA-approved, pharmaceutical product as covering its product.

28. Orange Book patent listings serve as a starting point for generic drug developers, manufacturers, and marketers, in making determinations about the viability of investing resources towards bringing a generic version of a branded, FDA-approved pharmaceutical to market.

29. Pursuant to 21 C.F.R. § 314.53, Braintree was required to submit FDA Form 3542 within thirty (30) days of the approval of the SUPREP NDA in order to list the '149 Patent in the FDA's Orange Book for the purpose of obtaining the benefits of the 30-month stay provided to NDA holders who list patents under the Hatch-Waxman Act.

30. 21 C.F.R. § 314.53 provides that only certain patents can be listed on FDA Form 3542 and in the Orange Book. Specifically, with respect to product claims, "[f]or patents that claim a drug product, the applicant shall submit information only on those patents that claim a drug product, as is defined in § 314.3, that is described in the pending or approved [NDA] application." For patents that claim a method of use, "the applicant

shall submit information only on those patents that claim indications or other conditions of use that are described in the pending or approved [NDA] application."

31. Braintree filed FDA Form 3542 with the FDA listing the '149 Patent as covering the drug approved in its NDA for SUPREP under both the product and use categories. With respect to SUPREP, the FDA listed the '149 patent in the Orange Book on or before October 1, 2010.

32. The Orange Book search page is found on the Internet at the URL http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. On that website, conducting a "Search by Proprietary Name" with the "Rx (Prescription Drug Products)" term "SUPREP" reveals NDA No. N022372, listing Braintree as the applicant. Clicking on that application number leads to a web page which shows that the New Drug Application for SUPREP was FDA approved on August 5, 2010, and provides another hyperlink to "View" "Patent and Exclusivity Info for this product." That hyperlink clicks through to Braintree's Orange Book listing claiming that SUPREP is covered by the '149 Patent for both a "Drug Product" claim and a method of treatment claim (referred to in the Orange Book as "Patent Use Code"), which Braintree listed as U-837, the code for GASTROINTESTINAL LAVAGE INDICATED FOR CLEANSING OF THE COLON AS A PREPARATION FOR COLONOSCOPY IN ADULTS.

33. The Orange Book entry for SUPREP does not list either Patent Use Code U-265, "USE AS A LAXATIVE," or Patent Use Code U-717, "METHOD OF RELIEVING OR PREVENTING CONSTIPATION IN A HUMAN CONSTIPATED PATIENT."

34. SUPREP is a gastrointestinal lavage product indicated for the cleansing of the colon as a preparation for colonoscopy in adults.

35. SUPREP is not indicated for use as a laxative or for relieving or preventing constipation in a human constipated patient.

36. The method claims of the '149 patent cover using gastrointestinal lavage products for the cleansing of the colon as a preparation for colonoscopy in adults.

37. The method claims of the '149 patent do not cover using gastrointestinal lavage products as a laxative or for relieving or preventing constipation in a human constipated patient.

38. FDA Form 3542 contains the following declaration in Section 6:

> The undersigned declares that this is an accurate and complete submission of patent information for the NDA . . . . This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct. Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

Following this warning is a line for the authorized signature of the NDA Applicant or holder or the patent owner.

39. An NDA holder's veracity in submitting Form 3542 is critical because upon receipt of the form, the FDA simply lists the patents shown on the form without any inquiry into the merits of the claim.

40. It is the FDA's position, upheld by the courts, that because it has no patent expertise, it does not have the ability to test the veracity of the listings, nor the obligation to do so. Accordingly, it is an FDA-approved NDA-holder—such as Braintree—and not the FDA, that decides what patents are listed as allegedly covering the approved product or use in the FDA Orange Book.

41. On information and belief, an authorized representative of Braintree signed Form 3542 in connection with its NDA for SUPREP listing the '149 patent.

42. Braintree's Orange Book listing is an advertisement to the public at large, including generic drug developers and manufacturers like Novel, that the '149 patent covers SUPREP.

43. Listing a patent in the Orange Book marks the identified drug with that patent.

44. Braintree launched SUPREP for commercial sale sometime in September or October 2010.

45. Braintree markets and sells SUPREP through pharmacies, hospitals, formularies and through other commercial channels, including on-line, in this Judicial District as well as throughout the country.

46. As marketed and sold, SUPREP packaging has FDA-approved exterior and interior labeling, including prescribing information, that each states, among other things, "U.S. Patent No. 6,946,149," marking the SUPREP product with the '149 patent.

C. ADMISSIONS AND STATEMENTS TO THE PUBLIC AND REGULATORY AGENCIES ESTABLISH BRAINTREE'S KNOWLEDGE AND UNDERSTANDING THAT THE CLAIMS OF THE '149 PATENT CANNOT COVER SUPREP

47. No claim of the '149 patent remaining after reexamination covers either (*i*) the product that the FDA approved in NDA No. 022372 for SUPREP, or (*ii*) the method of using that product for "cleansing of the colon as a preparation for colonoscopy in adults," the description of which is provided in the FDA-approved "Indications and Usage" section of the Full Prescribing Information for SUPREP.

1. STATEMENTS AND ADMISSIONS IN SCIENTIFIC ARTICLES

48. Braintree employee and co-inventor of the '149 patent Mark vB. Cleveland admitted to the public that the SUPREP solution has a volume of 960 ml, well outside the "from about 100 ml to about 500 ml" limitation recited in the claims of the '149 patent as amended after reexamination.

49. On or before November 26, 2008, Dr. Cleveland and several co-authors submitted an article to the *American Journal of Gastroenterology*, entitled, "A Randomized Clinical Study Evaluating the Safety and Efficacy of a New, Reduced-Volume, Oral Sulfate Colon-Cleansing Preparation for Colonoscopy" (the "Cleveland Article").

50. The Cleveland Article was accepted for publication on March 9, 2009, published online on July 7, 2009, and published in print in volume 104 of the *American Journal of Gastroenterology* in September 2009 at pages 2275-2284.

51. Dr. Cleveland admits in the Cleveland Article that he "sought to evaluate a new, low-volume, oral sulfate solution as a bowel preparation for colonoscopy in adult patients."

52. The Cleveland Article states:

> Gut lavage using large volume orally administered solutions has been developed as colon-cleansing preparations for diagnostic and surgical procedures. Because these solutions are isotonic and electrolyte balanced, there is little change in patient hydration and electrolytes in spite of the large volumes required. Up to four liters are required for effective purging resulting in patient complaints related to the volume of solution that must be ingested.

53. In the Cleveland Article, Dr. Cleveland admits that SUPREP is a "new 960-ml oral sulfate solution," and admits that this 960-ml solution is "effective for colonoscopy cleansing and has an acceptable safety profile."

54. In the Cleveland Article, Dr. Cleveland describes the effective preparation as follows:

> Oral sulfate solution (SUPREP, Braintree Laboratories) consists of sodium sulfate (35.0g), magnesium sulfate (3.2g), potassium sulfate (6.3g) and flavoring agents in aqueous liquid form supplied in two 6-ounce (oz) plastic bottles. The contents of each bottle are diluted with water to 16 oz and ingested. Bowel cleansing requires ingestion of both bottles of sulfate solution. The total preparation volume is 960 ml.

55. After describing the competing product (PEG-EA, trade name MoviPrep) as containing a preparation volume of 2,000 ml, the authors comment that "[b]oth preparations [i.e., 960 ml of SUPREP and 2,000 ml of PEG-EA] were packaged in identical outer containers to maintain the integrity of the treatment blind." Later, the Cleveland Article reconfirms that

> [t]he oral sodium salt solution (SUPREP) is composed of an aqueous combination of sodium, potassium and, (*sic*) magnesium salts of sulfate with appropriate flavoring yielding a preparation that delivers 29.67 g of sulfate anion . . . . The total dose is 960 ml.

Dr. Cleveland explained that PEG-EA was "selected as the control agent because it is a reduced volume preparation (requiring ingestion of 2 [liters] of solution). . . ."

56. The admissions of Dr. Cleveland—a co-inventor of the compositions and methods claimed in the '149 patent, and a participant in the development of SUPREP—clearly establish that SUPREP falls outside the '149 claim limitation requiring a composition comprising "from about 100 ml to about 500 ml of an aqueous hypertonic

solution comprising [consisting essentially of] an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4."

57. As one of Braintree's long-time senior executives, the admissions and understanding of Dr. Cleveland is fairly imputed to Braintree, thus establishing that Braintree knew that SUPREP falls outside the '149 claim limitation requiring a composition comprising "from about 100 ml to about 500 ml of an aqueous hypertonic solution comprising [consisting essentially of] an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4."

58. In describing the clinical studies performed to demonstrate SUPREP's efficacy and safety, the Cleveland Article states that the SUPREP preparation was given to subjects enrolled at twenty-one US study sites between July 16, 2007 and November 1, 2007. The Cleveland Article specifically references two phase III clinical trials registered at http://www.clinicaltrials.gov. The first, NCT00503607, tested a same-day administration of BLI-800 (SUPREP) against a PEG-based bowel preparation in about 400 patients between July 2007 and November 2007. The study measures efficacy outcome based on preparation quality—meaning the degree of colon cleansing—on a four-point scale, and safety outcomes based on a laboratory analysis of "preparation related side effects" after 30 days. The second, NCT00503815, tested a split-dose administration of BLI-800 (SUPREP) against a PEG-based bowel preparation in about 360 patients over the same time period and with the same outcome measures as NCT00503607.

59. The clinical studies described in the Cleveland Article constitute at least a portion of the clinical studies Braintree provided to the FDA in support of approval of NDA No. 022372 to market SUPREP.

60. The Cleveland Article describes the colon-cleansing study method for "study 1 (same day) at 1800 hours" as follows:

> sulfate [i.e., SUPREP] subjects were instructed to pour one 6-oz bottle of study medication into a provided 16-oz mixing cup. They would fill the cup with water and drink the entire volume. They were then instructed to drink two additional 16-oz cups of water over the next hour. At approximately 1900 hours, study subjects were instructed to pour the second 6-oz bottle of study medication into the 16-oz mixing cup, fill with water and drink. Over the next hour, they were instructed to drink an additional two 16-oz cups of water."

For "study 2 (split dose), sulfate subjects had the first bottle of the oral sulfate solution the evening before colonoscopy. The second bottle was given at approximately 0600 hours on the day of colonoscopy."

61. Each claim of the '149 patent contains a limitation requiring that "the composition does not produce any clinically significant electrolyte shifts." The Cleveland Article provides no evidence that the administration of the 6-ounce concentrated sulfate salt solution without additional water will ***not*** produce any clinically significant electrolyte shifts.

62. At least by the time of the publication of the Cleveland Article, Dr. Cleveland knew that the Cleveland Article provided no evidence that SUPREP administration without additional water "did not produce any clinically significant electrolyte shifts."

63. Co-inventor of the '149 patent, Dr. John S. Fordtran, has been associated with Braintree since at least as early as 1983. In or about 1983, Dr. Fordtran entered into a exclusive license agreement with Braintree to make, use and sell certain proprietary compositions for bowel cleansing prior to colonoscopy. Dr. Fordtran has assigned at least two patents naming him as an inventor to Braintree.

64. Dr. Fordtran was a co-author with other researchers on a scientific paper entitled, "Intestinal and Renal Effects of Low-Volume Phosphate and Sulfate Cathartic Solutions Designed for Cleansing the Colon: Pathophysiological Studies in Five Normal Subjects," published in the April 2009 edition of volume 104 of the *American Journal of Gastroenterology* at pages 953-965 (the "Patel Article"). Dr. Fordtran and his colleagues submitted the Patel Article for publication on or before February 20, 2008. The journal accepted the Patel Article for publication on October 13, 2008, and published it online on February 24, 2009.

65. Despite Braintree's identification of his claim to inventorship of the subject matter in the '149 patent in 2009, disclosing inventions made on or before April 30, 2002, Dr. Fordtran reports in the Patel Article that he and his co-authors "hypothesized that a concentrated low-volume sulfate solution would be an equally effective cathartic" compared to a low-volume phosphate solution.

66. In fact, according to the Patel Article, it is only "possible," as late as 2008-2009, "that a hypertonic solution of sulfate salts would meet the[ ] goals" of developing "a small volume, phosphate-free cathartic that would be as effective as phosphate, but less likely to cause kidney damage."

67. In their patent application dated April 30, 2002, however, Dr. Fordtran's co-inventor Dr. Cleveland discloses that

> I have found a safe and effective small volume colonic purgative formulation that avoids the problems of the prior art, using poorly absorbable sulfate salts with a small quantity of polyethylene glycol. In performing this research, my objective was to find a well tolerated orally administered colonic purgative that was as effective as the well known hypertonic phosphate

> ravages, that avoided the risks of upset of electrolyte balance in patients.

68. The sulfate salt composition tested in the Patel Article contained Na_2SO_4 (35.02 g), K_2SO_4 (6.26 g), and $MgSO_4$ (3.2 g).

69. The composition disclosed in the Patel Article is not SUPREP.

70. The Patel Article describes that "[a]nhydrous sodium and potassium sulfate were purchased from Mallinckrodt Baker," that "[a]nhydrous magnesium sulfate was purchased from Fisher Scientific," and that "[f]or each dose, the salts were dissolved in water, quantity sufficient to produce 100 ml of solution. No flavoring was added."

71. In the study reported in the Patel Article, two doses of the composition were administered to five patients. For each dose, the sulfate salt solution "was swallowed, and followed immediately with 250 ml of water. During the next 3 h, 1,630 ml of additional water was ingested in divided doses at 30 min intervals. Thus, with and after the ingestion of the two doses of sulfate salts, subjects ingested 3,960 ml of water."

72. The Patel Article specifically refers to volunteer subjects as "hydrated."

73. The Patel Article does not disclose the administration of the 100 ml concentrated sulfate salt solution without additional water.

74. On or before March 18, 2009, Dr. Cleveland, along with several co-authors, including Braintree employee Russell W. Pelham, Ph.D., submitted an article to the *Journal of Clinical Pharmacology*, entitled, "A Pharmacokinetics Evaluation of a New, Low-Volume, Oral Sulfate Colon Cleansing Preparation in Patients with Renal or Hepatic Impairment and Healthy Volunteers" (herein, the "Pelham Article"). The Pelham Article published in the March 2010 edition of volume 50 of the journal at pages 350-354.

75. The Pelham Article evaluated the pharmacokinetics of SUPREP, stating:

> The OSS (SuPrep, Braintree Laboratories Inc) consisted of sodium sulfate (35.0 g), potassium sulfate (6.3 g), magnesium sulfate (3.2 g), and flavoring agents, divided into two 6-oz liquid doses.

76. The Pelham Article administered SUPREP as a split-dose. Each six-ounce undiluted solution was diluted with water to 16 ounces and then consumed, followed by 2 additional 16-ounce cups of water within 1-3 hours after each dose.

77. Like the administered 960 ml solution described in the Cleveland Article, the Pelham Article describes SUPREP in the same manner, namely as a solution having a volume greater than 500 ml as administered to a subject.

78. The Pelham Article does not disclose administration of the undiluted SUPREP solution without additional water, and does not evaluate whether administration of the undiluted SUPREP solution without additional water produced clinically significant electrolyte shifts in a patient.

79. On or before January 5, 2010, Dr. Cleveland, along with several co-authors, submitted an article to the journal *Gastrointestinal Endoscopy*, entitled, "A Randomized Clinical Study Comparing Reduced-Volume Oral Sulfate Solution with Standard 4-Liter Sulfate-Free Electrolyte Lavage Solution as Preparation for Colonoscopy" (herein, the "Rex Article"). The Rex Article published in the August 2010 edition of the journal at pages 328-336.

80. The Rex Article reports a study comparing the efficacy of producing successful (i.e., good or excellent) bowel preparation with administration of SUPREP versus another solution. According to the Rex Article,

> OSS [SUPREP] is administered as a split-dose regimen, in which 6 oz of OSS is diluted in water to 16 oz, followed by 32 oz of water, and the regimen is repeated

> the following morning before colonoscopy. Therefore, the entire regimen involves a reduced volume of 32 oz preparation solution and 64 oz water, although additional fluid can be taken.

81. Dr. Cleveland, co-author of the Rex Article, admits that SUPREP is a 32-ounce preparation (approximately 946 ml), characterizing this preparation as a "reduced volume" preparation.

82. As administered to a patient, the Rex Article describes SUPREP as a solution having a volume greater than 500 ml.

83. The Rex Article describes serum chemistry data before and after administration of SUPREP:

> Two subjects in the OSS [SUPREP] group had increased serum phosphate immediately after preparation (Table 6). Both of these subjects had baseline serum phosphate levels of 3.7 mg/dL. The post preparation phosphate levels were 9.2 and 5.7 mg/dL, respectively. The redraw levels were 3.7 and 3.5 mg/dL, respectively, and neither patient had a change in serum creatinine from baseline. The patient with the phosphate level of 9.2 mg/dL had a postpreparation potassium level of 6.3 mEq/L.

The normal upper and lower and lower limits of the normal range for serum phosphate as reported in Table 7 of the Rex Article is 2.5-4.9 mg/dL. Both patients exhibited serum phosphate levels after SUPREP administration that exceeded the normal range. The normal upper and lower and lower limits of the normal range for serum potassium is 3.6-5.2 mEq/L. One patient exhibited serum potassium levels after SUPREP administration that exceeded the normal range.

84. The Rex Article demonstrates that SUPREP administration in two patients caused clinically significant electrolyte shifts, as that term is properly interpreted in light of the explicit definition in the '149 patent specification.

85. Dr. Cleveland and Braintree know that SUPREP administration in the clinical study described in the Rex Article produced clinically significant electrolyte shifts in two patients, and that SUPREP does not fall within the scope of the claims, each requiring that the "composition does not produce any clinically significant electrolyte shifts."

86. The term "Braintree's Scientific Articles" refers collectively to the Cleveland Article, the Patel Article, the Pelham Article, and the Rex Article. Braintree's Scientific Articles do not describe the administration of SUPREP, or an equivalent concentrated Na_2SO_4, K_2SO_4, and $MgSO_4$ solution, to a patient without the consumption of additional water. None of Braintree's Scientific Articles determined whether an undiluted sulfate salt solution, such as the two six-ounce bottles of undiluted solution provided in a SUPREP kit, could cause clinically significant electrolyte shifts.

87. As stated in Braintree's Scientific Articles, co-inventors Dr. Cleveland and Dr. Fordtran admit and know that SUPREP does not fall within the scope of the "from about 100 ml to about 500 ml" limitation present in each of the claims of the '149 patent.

88. Given his senior executive position and long-time employment with Braintree, Dr. Cleveland's admissions and knowledge, in particular, about SUPREP, can be, and is imputed to Braintree.

89. Braintree, either on its own or through Dr. Cleveland, knows and admits that SUPREP falls outside the '149 claim limitation requiring a composition comprising "from about 100 ml to about 500 ml of an aqueous hypertonic solution comprising [consisting

essentially of] an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4."

90. On information and belief, neither Braintree nor any of the authors on any of Braintree's Scientific Articles ever performed any clinical studies of an undiluted SUPREP solution (or equivalent concentrated sulfate salt solution) to determine whether it would produce any clinically significant electrolyte shifts in a patient.

91. Braintree, either on its own or through Dr. Cleveland, knows that there is no evidence supporting the lack of any clinically significant electrolyte shifts upon administration of SUPREP without additional water. Braintree furthermore knows that SUPREP falls outside the '149 claims, because each claim requires that "the composition does not produce any clinically significant electrolyte shifts."

92. Braintree never reported the existence or results of a clinical study involving administration of an undiluted SUPREP solution (or equivalent concentrated sulfate salt solution) to a patient to the FDA.

93. On information and belief, a patient could experience clinically significant electrolyte shifts if the patient drinks the six-ounce SUPREP solution (or equivalent concentrated sulfate salt solution) without diluting it with water.

94. On information and belief, a patient could experience clinically significant electrolyte shifts if the patient drinks the six-ounce SUPREP solution (or equivalent concentrated sulfate salt solution) without drinking about one liter or more of water after administering the six-ounce SUPREP solution.

95. On information and belief, unless a patient drinks thirty-two ounces of additional water after the administration of a six-ounce SUPREP solution diluted with ten ounces of water, a patient could experience clinically significant electrolyte shifts.

96. Braintree Director of Pharmacology and Toxicology, Dr. Russell W. Pelham, co-authored an article entitled "Split-Dose Bowel Cleansing and Clinical Considerations of Sedation Prior to Colonoscopy." The article was sponsored by Braintree, and published by McMahon Publishing in September 2011 as a Special Report of Gastroenterology & Endoscopy News.[1] In this September 2011 article, Dr. Pelham repeats the warning, consistent with the understanding and knowledge of Braintree and his colleague Dr. Cleveland, that

> [a]ll patients should be advised to hydrate adequately before, during and after the use of SUPREP. Each bottle of SUPREP must be diluted to a final volume of 16 ounces, and ingestion of additional water as recommended is important to patient tolerance. Direct ingestion of the undiluted solution may increase the risk for nausea, vomiting, dehydration, and electrolyte disturbances.

97. As disclosed in the Rex Article, however, SUPREP administration, even with the additional water required by the FDA-approved label, can produce clinically significant electrolyte shifts.

98. Dr. Cleveland knows that SUPREP administration has produced clinically significant electrolyte shifts in at least two patients.

99. Braintree knows that SUPREP administration has produced clinically significant electrolyte shifts in at least two patients.

[1] Available at http://www.gastroendonews.com/download/SR1132_BraintreeColonoscopy_WM.pdf.

100. Dr. Cleveland knows that SUPREP administration has produced "clinically significant electrolyte shifts," as that phrase is properly interpreted in the claims of the '149 patent, in at least two patients.

101. Braintree knows that SUPREP administration has produced "clinically significant electrolyte shifts," as that phrase is properly interpreted in the claims of the '149 patent,

2. STATEMENTS AND ADMISSIONS TO THE FDA

102. On or around July 1, 2008, Braintree submitted a NDA to the FDA seeking approval to market SUPREP. The NDA provided "for the use of SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate, magnesium sulfate) Oral Solution for cleansing of the colon in preparation for colonoscopy in adults."

103. The Director of the Division for Gastroenterology Products in the FDA's Center for Drug Evaluation and Research, Donna Griebel, M.D., filed a summary review of NDA No. 022372 for SUPREP on August 5, 2010 (the "Summary Review"). The Summary Review recommended approval of the SUPREP NDA.

104. Characterizing Braintree's description of SUPREP, the Summary Review states that the SUPREP Bowel Prep Kit

> consists of a carton that contains two equal doses (6 oz) of 17.5 g sodium sulfate, 3.13 g potassium sulfate and 1.6 g magnesium sulfate in each of the 6 oz bottles. The bottled solutions are further diluted before the patient drinks them. The applicant proposes . . . dose schedules . . . studied in phase 3 clinical trials. In the "Split dose" regimen the patient dilutes the contents of one of the 6 oz bottles to 16 oz, drinks the diluted solution . . . and follows with two additional 16 oz "cups" of water . . . . The sequence is then repeated with the second 6 oz bottle, 12 hours after the first dose.

In addition, the Summary Review stated that SUPREP "requires further dilution for use." The Summary Review specifically noted that Braintree originally proposed labeling including "a warning not to drink the solution undiluted."

105. The Summary Review reflects Braintree's awareness and understanding that SUPREP must be diluted to a volume of at least 32 oz (approximately 946 ml) for safe administration to a patient.

106. In the Summary Review, phosphate is documented as an electrolyte outside the range of normal in any subject treated with the sulfate prep (1 high phosphate in the "Split dose" group and 2 high phosphates in the "Same day/evening only" group), all observed at 22 hour blood sample.

107. Evaluating the two major phase III clinical trials supporting NDA No. 022372, studies 301 and 302, each comparing SUPREP to MoviPrep, the Summary Review considered the "frequencies of serum chemistry results that fell outside the range of normal in the combined study populations." The Summary Review compiled a table of the incidence of abnormal chemistry results in patients whose baseline levels were normal in the following table:

Table 19: Combined Studies 301 & 302: Incidence of Abnormal Chemistry Results in Patients with Normal Values at Screening Visit (Only Events with Proportion ≥ 5% for Suprep)

	Bicarb ↓	Ca ↑	Gluc ↑	bili ↑	T. prot ↑	Uric Acid ↑
Suprep	11%	7.2%	9.6%	9.1%	5.1%	26%
MoviPrep	15%	2.7%	11.1%	13.2%	1.1%	12%

Derived from Applicant's Table 14.3.6.1, p. 137-139 in vol. 8.1 of Module 5.

This table, derived from data presented in Braintree's own application, shows that SUPREP administration causes clinically significant electrolyte shifts with regard to bicarbonate and calcium ions. The FDA's Summary Review therefore establishes the existence of "clinically

significant electrolyte shifts" as that phrase is properly interpreted in the '149 patent claims, in several patients enrolled in its phase III clinical trials.

108. The Summary Review states that, for bicarbonate, the "lower limit of normal was 22 for the central laboratory," and that for a single patient to whom SUPREP was administered, measurements "dropped to a serum bicarbonate of 11 and returned to 21 (still just below the lower limit of normal) on Day 30."

109. The Summary Review presented an overall summary of safety stating that the "[e]vidence suggests a relationship between Suprep and the number of subjects for whom calcium falls outside the range of normal (high/low)," and the "[e]vidence suggests that for both Suprep and Moviprep the "Split dose" regimen is related to more subjects with abnormal calcium values (high/low)."

110. The Summary Review therefore confirms Braintree's observation of clinically significant electrolyte shifts after SUPREP administration.

111. On or after August 5, 2010, Braintree's Director of Regulatory Affairs, Vivian A. Caballero, received a letter announcing the approval of NDA No. 022372 and attaching the approved labeling materials referenced elsewhere in this pleading.

112. The FDA-approved labeling for SUPREP provides that after adding ten ounces of water to the six-ounce SUPREP composition that comes in Braintree's packaged product, and drinking that 16-ounce composition (approximately 473 ml), "You MUST drink two more 16-ounce containers of water over the next hour."

113. The FDA-approved prescribing information for SUPREP in the "Dosage and Administration" section states, "SUPREP Bowel Prep Kit should be taken as a split-dose oral regimen. The dose for colon cleansing requires administration of two bottles of SUPREP

Bowel Prep Kit. Each bottle is administered as 16 oz of diluted SUPREP solution with an additional 1 quart of water taken orally. The total volume of liquid required for colon cleansing (using two bottles) is 3 quarts (approximately 2.8 L) taken orally prior to the colonoscopy in the following way: . . . ."

114. The "Dosage and Administration" set forth in the SUPREP prescribing information is the dosage and administration that Braintree and the FDA consider to be safe and effective for cleansing of the colon as a preparation for colonoscopy in adults.

115. The SUPREP web site contains additional information concerning the importance of diluting SUPREP and hydration:

> Can I drink SUPREP directly from the bottle it comes in?
>
> No. Each bottle of SUPREP must be mixed with water (diluted) before you drink it. It is important for you to drink the additional prescribed amount of water listed in the instructions for Use to prevent fluid loss (dehydration). Drinking SUPREP without diluting it may increase the risk of nausea, vomiting, fluid loss (dehydration) and electrolyte disturbances. Please carefully read and follow the instructions in the SUPREP Bowel Prep Kit about how to dilute and take SUPREP.
>
> * * *
>
> Advise all patients to hydrate adequately before, during, and after use. Each bottle must be diluted with water to a final volume of 16 ounces and ingestion of additional water as recommended is important to patient tolerance.

116. By clicking on the link "How to Prepare?" the web site explains that "[i]t is important to follow all the steps below completely:"

Both 6-ounce bottles are required for a complete preparation.

IT IS IMPORTANT TO FOLLOW ALL THE STEPS BELOW COMPLETELY.

Step 1:	
	Pour **ONE** (1) 6-ounce bottle of SUPREP liquid into the mixing container.
Step 2:	
	Add cool drinking water to the 16-ounce line on the container and mix. **NOTE:** Be sure to dilute SUPREP as shown at left before you drink it.
Step 3:	
	Drink **ALL** the liquid in the container.
Step 4:	
	You **must** drink two (2) more 16-ounce containers of water over the next 1 hour. **NOTE:** You **must** finish drinking the final glass of water at least 1 hour, or as directed, before your procedure.

117. Without adequate dilution and hydration while taking SUPREP, a patient could experience clinically significant electrolyte shifts.

118. On or around April 9, 2010, Braintree received a letter from the FDA requesting a list of patients who developed low serum bicarbonate on study and were normal at baseline. The letter also requested information on lab abnormalities for, among other things, hypocalcemia, hypercalcemia, and low serum bicarbonate in patients who did

not have an abnormal laboratory finding at baseline. Braintree provided a response to this request on or around April 19, 2010.

119. Braintree knew that SUPREP administration during clinical trials led to levels of bicarbonate and/or calcium that were outside the upper and lower limits of their normal range in at least one subject and reported this information to the FDA.

120. Braintree knew that SUPREP administration during clinical trials produced at least one clinically significant electrolyte shift in at least one subject and reported this information to the FDA.

121. Administering a composition containing sodium sulfate 35.0 g, potassium sulfate 6.26 g and magnesium sulfate 3.2 g in an aqueous hypertonic solution having a volume of less than about a 500 ml solution will produce clinically significant electrolyte shifts in at least one patient.

122. Braintree knows that administering a composition containing sodium sulfate 35.0 g, potassium sulfate 6.26 g and magnesium sulfate 3.2 g in an aqueous hypertonic solution having a volume of less than about a 500 ml solution will produce clinically significant electrolyte shifts in at least one patient.

3. BRAINTREE'S ADMISSIONS TO THE PTO

123. After the FDA approved NDA No. 022372 for SUPREP, on or around September 30, 2010, Braintree filed a Request for Extension of Patent Term under 35 U.S.C. § 156 with the PTO (the "PTE Request").

124. In the PTE Request, Braintree admitted that SUPREP is the approved product relevant to the request for extension of patent term of the '149 patent. Braintree also admitted that SUPREP is approved for oral administration as an osmotic laxative for

cleansing of the colon in preparation for colonoscopy in adults. Braintree also admitted that SUPREP "is administered as follows: Evening before colonoscopy: dilute 1 bottle to 16 oz with water and drink entire amount; Drink 32 oz water over the next hour; Next morning repeat both steps using the second bottle; Complete preparation at least 1 hour before colonoscopy."

125. 37 C.F.R. § 1.740(9) requires a statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing that demonstrates the manner in which at least one patent claim reads on the approved product or a method of using or manufacturing the approved product.

126. In the PTE Request, Braintree told the PTO that "U.S. Patent No. 6,946,149 claims the Approved Product [SUPREP]. Specifically, claims 15-21 and 23 read on the Approved Product."

127. In the PTE Request, Braintree admitted that SUPREP is an osmotic laxative for cleansing (i.e., purging) of the colon, as evidenced by the approved label.

128. Braintree further admitted that

> [t]he SUPREP product comprises a small volume. Specifically, the product contains only 2 x 16 ounces of solutions (i.e., approximately 2 x 0.4 L = .94 L of solution) as indicated in the approved label.

Braintree explained that "a small volume" is defined as a volume of less than one liter of water.

129. Braintree represented to the PTO that the SUPREP product is not covered by the claim element "from about 100 ml to about 500 ml."

130. Braintree knew that the SUPREP product is not covered by the claim element "from about 100 ml to about 500 ml."

131. According to the PTE Request,

> Braintree Laboratories, Inc. acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

132. In neither the PTE Request, nor, upon information and belief, at any time, has Braintree disclosed to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services that at least one patient taking SUPREP experienced clinically significant electrolyte shifts.

133. In neither the PTE Request, nor, upon information and belief, at any time, has Braintree disclosed to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services that, upon information and belief, Braintree has no evidence that administration of undiluted SUPREP to a patient without dilution or the additional water required by the FDA-approved label will not produce clinically significant electrolyte shifts.

D. BRAINTREE FALSELY MARKED SUPREP WITH THE '149 PATENT WITH DECEPTIVE INTENT

134. By listing the '149 patent in the Orange Book and marking its product inserts with the '149 patent, Braintree falsely marked its prescription SUPREP product under 35 U.S.C. § 292. Braintree listed the '149 patent in the Orange Book as covering SUPREP and marked the '149 patent on its product inserts for SUPREP with an intent to deceive the public.

1. FACTUAL EVENTS LEADING TO BRAINTREE'S DEVELOPMENT OF A PRODUCT, SUPREP, NOT COVERED BY THE CLAIMS OF THE '149 PATENT

135. Prior to SUPREP's approval, Braintree marketed three gastrointestinal lavage products indicated for bowel cleansing prior to colonoscopy: (*i*) GoLYTELY® (PEG-based),

introduced in 1984; (*ii*) NuLYTELY® (PEG-based), a reformulation of GoLYTELY, introduced in 1999; and (*iii*) HalfLytely® (PEG-based plus bisacodyl tablets), "the first low-volume GI lavage," introduced in 2004.

136. Upon information and belief, Dr. Fordtran (with Dr. Glenn Davis) developed the formula for GoLYTELY in the early 1980s.

137. Upon information and belief, in or about 1983, Drs. Fordtran and Davis entered into a license agreement with Braintree, granting Braintree the exclusive right to make, use and sell the GoLYTELY formula and to use the GoLYTELY mark in return for royalties and other obligations as long as those products were sold. Upon information and belief, since that original agreement, Drs. Fordtran and Davis subsequently modified the formulation and agreed to permit Braintree to sell this reformulated solution under the mark NuLYTELY, paying Drs. Fordtran and Davis royalties on sales of both products.

138. Upon information and belief, HalfLytely, Braintree's reduced-volume product introduced in 2004, is, in fact, NuLYTELY in a reduced quantity, effective for bowel cleansing when taken together with the stimulant laxative bisacodyl in tablet form.

139. Upon information and belief, Braintree marketed and sold HalfLytely, which includes Drs. Fordtran and Davis' proprietary formula also used in NuLYTELY, from at least 2004 until at least January 31, 2006, during which time Braintree did not pay Drs. Fordtran and Davis royalties.

140. Drs. Fordtran and Davis sued Braintree in Texas state court on or around January 31, 2006, alleging breach of contract. Braintree filed a notice of removal of the case to the Northern District of Texas on February 23, 2006.

141. Upon information and belief, Braintree sought to develop another "low volume" bowel cleansing preparation that would not be subject to its prior licensing agreement with Drs Fordtran and Davis.

142. Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines, making development of a new drug difficult. An Investigational New Drug Application ("IND") allows a sponsor of a potential new drug to obtain an exemption from the FDA to ship the investigational drug to clinical investigators in various states to determine both the drug's safety for initial use in humans and whether the drug exhibit pharmacological activity that justifies commercial development.

143. While the lawsuit filed by Drs. Fordtran and Davis was pending in federal court, on or around April 6, 2006, Braintree submitted an original IND, assigned No. 74808, covering an Oral Sulfate (Magnesium, Sodium, Potassium) Solution.

144. Upon information and belief, prior to its filing of IND No. 74808, Braintree did not attempt to develop an oral solution containing sodium sulfate, potassium sulfate and magnesium sulfate into a commercial product.

145. Upon information and belief, Braintree focused on Solution D, disclosed in the '149 patent as effective for producing colonic purgation (i.e., cleansing) in preparation for colonoscopy, as a new low-volume alternative to its HalfLytely product. Upon information and belief, Solution D was more attractive than Solution E, also effective, because Solution E included PEG, the development of which might require a license and be subject to royalty payments to Dr. Fordtran who, at that time, was not listed as an inventor on the '149 patent. Upon information and belief, the mixture of sulfate salts provided by

Solution D allowed Braintree to develop a product unencumbered by royalty obligations to Dr. Fordtran.

146. On or around April 26, 2006, a clinical trial called BLI800-101 involving an Oral Sulfate (Magnesium, Sodium, Potassium) Solution commenced at the Kendle Clinical Pharmacology Unit in Utrecht, The Netherlands. Dr. Alina Dobre was the Principal Investigator for the trial. According to clinical trial BLI800-101, compositions were administered in a total volume of 2480 ml, and additional water was allowed ad libitum.

147. Braintree submitted BLI800-101 to the FDA in support of NDA No. 022372 for SUPREP.

148. After April 30, 2002, the filing date of the application that gave rise to the '149 patent application, and, upon information and belief, at least as early as April 2006, Braintree knew that safety considerations would dictate that a sufficient amount of water be administered with any "low-volume" hypertonic sulfate solution to avoid clinically significant electrolyte shifts.

149. This understanding is reflected in the conclusions of BLI800-101, in which an experimental Oral Sulfate Solution ("OSS") (different from SUPREP) was evaluated with an Oral Phosphate Solution ("OPS") as a positive control. A summary of BLI800-101 reported that

> The mean fluid balance was positive for all groups; total water intake was higher than water loss. Subjects receiving OPS appeared to be thirstier which may indicate that OSS causes less dehydration than OPS and less disturbances in electrolytes.

150. Upon information and belief, Braintree did not commercially develop the salt solutions for colon cleansing purportedly invented by Drs. Cleveland and Fordtran

(notwithstanding Dr. Fordtran's omission from the patent application) in the '149 patent prior to 2006.

151. Upon information and belief, a different solution and preparation from those disclosed in the '149 patent was necessary to produce a product having a safety and efficacy profile sufficient to ensure FDA approval.

152. The existence of different formulations is evident from Braintree's disclosures to the FDA in clinical trial BLI800-101, a study describing the use of a solution that differs from Solution D of the '149 patent and also differs from the approved SUPREP solution.

153. In the course of clinical development, additional clinical trials were conducted that Braintree relied upon in support of the SUPREP NDA. Among these other studies were two phase III clinical trials, BLI800-301 and BLI-302. These two clinical trials studied solutions that differ from those disclosed in the '149 patent.

154. Despite results from the clinical trials showing clear evidence of clinically significant electrolyte shifts, the drug development process had advanced to a stage that made it economically impractical to change the solution, formulation, or administration of SUPREP.

2. BRAINTREE'S KNOWLEDGE AND UNDERSTANDING

155. Braintree's knowledge of the SUPREP product, at all relevant times to this inquiry is evidenced by its statements made to the FDA or the FDA's conclusions reached after reviewing Braintree's submissions in support of NDA No. 022372 for SUPREP.

156. Braintree is an extremely sophisticated pharmaceutical company that employs in-house counsel and regularly litigates patent-infringement cases under the

Hatch Waxman Act. As such, Braintree knows, or reasonably should know, of the requirements of 21 U.S.C. § 355, 21 C.F.R. § 314.53 and 35 U.S.C. § 292.

157. Braintree knows that patents provide the patent holder with market exclusivity of the claimed invention. Braintree knows that all exclusive rights in a patent are limited to the subject matter claimed in the patent. Braintree knows that listing, advertising and/or marking SUPREP with false patent statements was, and is, in derogation of its obligations to be truthful to the FDA.

158. An article is "unpatented" under the false marking statute if not one claim of the allegedly covering patent "reads on" the article in question.

159. Braintree knows that an article is "unpatented" under the false marking statute if not one claim of the allegedly covering patent "reads on" the article in question.

160. As a sophisticated entity that has relied on the benefits of patent protection in the past, Braintree knows and understands that a patent claim covering a product "reads on" an accused infringing article when that article possesses each and every element of the claim, thus giving rise to liability for infringement of that claim.

161. Braintree further understands that a patent claim covering a method "reads on" an accused use when a person practices each and every step of the claimed method, thus giving rise to liability for infringement of that claim.

162. Although they are not patent lawyers, Braintree employees Drs. Cleveland and Pelham know and understand the basic legal foundations concerning patent claim interpretation and infringement analyses.

163. In at least 2000, and upon information and belief, at other times relevant to the facts alleged herein, Drs. Cleveland and Pelham were in direct and frequent contact

with Braintree's patent counsel, with Dr. Pelham speaking to Braintree's patent counsel about five to ten times per month. In 2001, Dr. Pelham authored and received many communications from the law firm of Cesari & McKenna LLP, the law firm responsible for filing the utility application that gave rise to the '149 patent. Dr. Cleveland was copied on many of these communications. Based on these facts, Drs. Cleveland and Pelham are well-versed in the relevant aspects of patent law concerning an infringement analysis.

164. As a sophisticated applicant, Dr. Cleveland in particular understood the legal effect of providing a clear and unambiguous definition for the term "clinically significant" in the application that gave rise to the '149 patent.

165. As set forth above, Braintree has repeatedly admitted that the SUPREP solution approved by the FDA in NDA No. 022372 is greater than the "from about 100 ml to about 500 ml" volume required by any of the relevant claims of the '149 patent.

166. As set forth above, Braintree has submitted several clinical trials and received analyses from the FDA's reviewers that clearly indicate the existence of "clinically significant electrolyte shifts" when SUPREP is administered to a subject in the manner called for in the FDA-approved prescribing information.

167. Upon information and belief, Braintree has not conducted studies to determine whether administration of either two six-ounce undiluted SUPREP solutions or two 16-ounce diluted SUPREP solutions without additional water do not produce clinically significant electrolyte shifts in a subject.

168. Braintree has wrongfully, illegally, and falsely listed, advertised and/or marked its SUPREP product as under a patent monopoly that it does not possess for FDA-

approved SUPREP, and, as a result, Braintree has wrongfully benefited by maintaining an unlawful market advantage.

169. A false patent marking combined with knowledge that the marking is false, or a lack of a reasonable belief that the false marking is true, gives rise to a presumption that the false marking was made "for the purpose of deceiving the public." The fact of misrepresentation coupled with proof that the party making it had knowledge of its falsity is enough to warrant drawing the ***inference*** that there was a fraudulent intent.

170. For at least the reasons set forth above, the '149 patent does not cover SUPREP as applied for and approved in Braintree's NDA application, Braintree (including named inventor and Braintree employee Dr. Mark Cleveland) has actual knowledge that the '149 patent does not cover SUPREP as applied for and approved, for example, as demonstrated by the statements in the Cleveland Article, on Braintree's web site, and in the SUPREP product insert, and Braintree has, in a continuous manner from at least September 2010 through the present, falsely advertised that the '149 patent covers SUPREP as marketed and approved by the FDA.

171. Specifically, with the actual knowledge that the '149 patent did not cover the product or methods of administration of the SUPREP product that Braintree applied to have approved by the FDA, Braintree nevertheless filed a false declaration to the FDA on Form 3542 claiming that the '149 product covered SUPREP, thereby obtaining the benefits of the 30-month stay provided by the Hatch-Waxman Act.

172. By advertising in the Orange Book and on its product inserts that the '149 patent covers SUPREP and its administration, Braintree intended to, and did, quell competition in the United States market for SUPREP by false marking and by improperly

manipulating the regulatory scheme provided for by the Hatch-Waxman Act in a manner that effectively and substantially delays the marketing of a generic version of SUPREP, specifically, by Novel.

173. Taken together, the foregoing facts establish that Braintree has intentionally deceived the FDA and the public as to the applicability of the '149 patent to the SUPREP product approved by the FDA and marketed by Braintree, by illegally listing/advertising the patent in its Orange Book patent listing for SUPREP and on its package inserts. Braintree's purpose for illegally advertising/listing in the Orange Book and on its package inserts that the '149 patent covers SUPREP is to quell competition in the United States market for its approved SUPREP product.

174. Braintree's false Orange Book advertising/listing of the '149 patent for its FDA-approved SUPREP product has wrongfully quelled competition with respect to such products, thereby causing harm to Novel, the United States, and the public-at-large.

175. Despite the fact that, as set forth above, Braintree knew that no claim of the '149 patent covers SUPREP or its use, Braintree was motivated to intentionally mark SUPREP with the '149 patent anyway to capture a stake in the market for small volume colon cleansing preparations prior to colonoscopy.

176. Upon information and belief, Braintree intentionally falsely marked SUPREP with the '149 patent to mislead the public and its competitors into believing that SUPREP falls within the scope of the '149 patent claims, and to avail itself of a monopoly over this product for the lifetime of the patent.

177. Braintree has used patent litigation under the Hatch-Waxman statutory scheme in the past as a means of excluding competition with other products.

178. On May 16, 2003, Braintree brought a patent infringement suit against Schwarz Pharma, Inc. ("SPI") after its filing of an ANDA to market a generic version of the Braintree's PEG-based constipation product, Miralax® (the "Miralax litigation").

179. The Miralax litigation involved U.S. Patent No. 5,710,183 (the " '183 patent"), issued to George M. Halow. In 1999, Dr. Halow had granted Braintree in a non-exclusive license to claim 33 of the '183 patent in exchange for a lump-sum fee of $15,000. The FDA approved Miralax shortly thereafter, and soon after that, Braintree listed the '183 patent in the Orange Book.

180. An internal memo by Braintree's Dr. Pelham described the '183 patent as "weak," and Dr. Fordtran, then acting as Braintree's consultant, first began working on a PEG-alone formulation to treat constipation back in 1985, ten years before the date of the Halow invention. In fact, Braintree's patent counsel concluded that claim 33 of the '183 patent would be found invalid in view of the prior art. At trial, SPI asserted that Braintree relied upon a patent that their own employees and agents admitted was weak.

181. Although the court ultimately did not find that the lawsuit was "objectively baseless" to support SPI's antitrust counterclaims, the court declined to hold that Braintree established a good faith basis for filing the lawsuit.

182. The Miralax litigation demonstrates that Braintree has relied upon patent litigation to advance its commercial interests and quash competition based on weak patents.

183. In this action, Braintree relies upon a weak patent—the '149 patent—to exclude its competitors, like Novel, from the marketplace for SUPREP. As set forth above, Braintree knows that SUPREP does not fall within the claim elements "from about 100 ml

to about 500 ml" or "does not produce any clinically significant electrolyte shifts," yet despite this knowledge, Braintree intentionally and falsely listed the '149 patent in the Orange Book and likewise marked the SUPREP product with the '149 patent.

E. NOVEL'S COMPETITIVE INJURY AND RECOVERY OF DAMAGES

184. Novel is an actual competitor of Braintree.

185. Novel has a direct commercial interest in protecting against harm caused by abuses of the patent system and the FDA Orange Book by Braintree.

186. False marking harms legitimate competitors by exerting a chilling effect on their willingness to enter the market for, or improve upon, the falsely-marked product. Such false designations force legitimate competitors and innovators to spend scarce resources to investigate and disprove these false assertions.

187. Braintree's false marking has also injured the market for the relevant product in general by introducing false information about Braintree's product to consumers and actual or potential competitors.

188. Braintree's false marking has also injured consumers by falsely perpetuating a superior brand associated with innovativeness, implying that their product or claims associated therewith have been reviewed, or approved by the federal government, or implicitly threatening actual or potential competitors with allegations of patent infringement. Further, the act of false marking misleads the public into believing that a patentee controls the article in question (as well as like articles), externalizes the risk of error in determining whether a patentee controls the article in question, placing the burden and risk of that determination on the public rather than the manufacturer or seller of the article, and increases the cost to the public of ascertaining whether a patentee in fact

controls the intellectual property embodied in an article. Thus, interests generally represented by Novel have been injured by Braintree's false patent marking.

189. Novel has suffered, and will continue to suffer, damages caused by Braintree's intentional false marking of SUPREP with the '149 patent. Novel has incurred costs associated with this litigation, including attorneys fees, which, but for Braintree's false marking, could not have brought. Novel will continue to bear damages relating to defending against Braintree's infringement allegations.

190. Braintree's false marking of SUPREP with the '149 patent, and in particular, its listing the '149 patent in the Orange Book, has also damaged Novel to the extent that this listing delays the approval of Novel's ANDA application to market a generic version of SUPREP.

191. Novel seeks recovery for these damages, as well as its reasonable attorneys' fees and costs associated with pursuing these legal claims, and other relief the Court find just and equitable.

FOURTH COUNTERCLAIM

(Violation of 15 U.S.C. § 1125(a))

192. Paragraphs 1-191 are hereby incorporated by reference as if fully set forth here.

193. As alleged above, Braintree's actions in falsely marking SUPREP with the '149 patent, and listing the '149 patent in the Orange Book in connection with SUPREP, constitute unfair competition and false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

194. As alleged above, Braintree knew that SUPREP was not and could not be covered by one or more claims of the '149 patent, yet has neither changed its product packaging to eliminate reference to the '149 patent, nor delisted the '149 patent in the Orange Book.

195. Upon information and belief, Braintree has gained profits from its false marking of SUPREP with the '149 patent by preventing its potential competitors from entering the market.

196. Novel has sustained damages as a result of Braintree's false marking with the '149 patent.

197. Novel has been and will continue to be irreparably harmed and damaged by Braintree's conduct insofar as Novel is prevented from entering the marketplace with a competing product due to the association of the '149 patent with SUPREP, and Novel lacks an adequate remedy at law to compensate for this harm and damage. Pursuant to 15 U.S.C. § 1116, Novel is entitled to an injunction against Braintree's continued false marking of SUPREP with the '149 patent, and unless enjoined, Braintree will continue falsely marking SUPREP with the '149 patent that will continue to injure Novel and the public.

198. Because Braintree's actions have been willful, Novel is entitled to a declaration that this is an exceptional case, justifying an award of reasonable attorneys fees pursuant to 15 U.S.C. § 1117(a).

FIFTH COUNTERCLAIM

(Counterclaim for Unfair Competition)

199. Paragraphs 1-198 are hereby incorporated by reference as if fully set forth here.

200. As alleged above, Braintree has made representations to the public, or caused such representations to be made, that SUPREP is covered by one or more claims of the '149 patent, and as a consequence, Braintree is entitled to exclude others from making, using or selling SUPREP.

201. As alleged above, the '149 patent does not cover SUPREP or its use.

202. Novel has made substantial investments in anticipation of selling and marketing an oral sulfate solution for use in colon cleansing prior to colonoscopy in patients.

203. Braintree's misrepresentation that the '149 patent covers SUPREP has impaired Novel's ability to implement its business plans and, upon information and belief, will result in damage and loss to Novel.

204. The acts and conduct of Braintree, as alleged above, constitute unfair competition and unfair business practices contrary to the laws of the State of New Jersey.

205. As a direct, proximate, and foreseeable result of the actions of Braintree, Novel has suffered and will continue to suffer monetary harm.

206. The acts and conduct of Braintree, as alleged above, have damaged Novel and has resulted in damages in an amount that is unknown at the present time.

207. Upon information and belief, Braintree's conduct has caused, and unless restrained by this Court will continue to cause, immediate and irreparable harm to Novel's anticipated financial interest and business.

PRAYER FOR RELIEF

WHEREFORE, Novel respectfully requests that this Court enter an Order:

(a) Declaring that Novel's product set forth in ANDA No. 202511 does not infringe the claims of the '149 patent;

(b) Declaring that the claims of the '149 patent are invalid;

(c) Finding that Braintree's listing in the Orange Book, manufacture, promotion, advertising, marketing, sale and/or distribution of products with false patent markings or false patent assertions violates 35 U.S.C. §292(b) as amended by Public Law No. 122-29;

(d) Declaring that Braintree has violated Section 43(a) of the Lanham Act entitling Novel to damages and injunctive relief;

(e) Declaring that Braintree has violated unfair competition laws of the State of New Jersey and that Novel was damaged therefrom;

(f) Awarding Novel damages to compensate for competitive injury resulting from Braintree's falsely marking its SUPREP product with the '149 patent;

(g) Declaring that this is an exceptional case within the scope of 15 U.S.C. § 1117(a);

(h) Awarding Novel its attorneys' fees and costs; and

(i) Directing all other relief that the Court finds just and proper.

REQUEST FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b)(1), Novel hereby demands a jury trial on all issues so triable on its Counterclaims.

November 29, 2011
New York, New York

Respectfully submitted,

ROBINS, KAPLAN, MILLER & CIRESI LLP

/s/ Hillel I. Parness

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